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09/914,441	08/27/2001	Hitoshi Kanazawa	14840	3997

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EXAMINER
BERMAN, SUSAN W

ART UNIT	PAPER NUMBER
1711	

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8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,441	Applicant(s) KANAZAWA, HITOSHI	
	Examiner Susan W Berman	Art Unit 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-53,55,56 and 59* is/are rejected.

7)☒ Claim(s) *54 and 57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendments and Arguments

Applicant argues that the comparative data in the specification shows that the instantly claimed process produces a product wherein many binding points, rather than few binding points, are formed between the hydrophilic polymer and the activated polymer material and that graft polymerization is facilitated by providing several functional groups for initiation of grafting. The data in the specification has been considered. The data shows a significant difference in percent water absorption for the examples compared with the comparative examples. However, comparative example 1 is not considered to be representative of the disclosure of JP '183 because no persulfate initiator was used in the process of comparative example 1. Furthermore, Example 1 according to the instantly claimed invention is not comparable with comparative example 1 because there are too many variables, i.e different polypropylene fabrics, different amounts of PVA, ozone treatment vs, no ozone treatment and use of cerium ammonium nitrate vs. no initiator. Example 4 of the instantly claimed invention can be compared with comparative example 1. Comparative example 2 could be compared with Example 6 of the instantly claimed invention. However, applicant has not pointed out cited prior art represented by either of the comparative examples. not resist many thermal treatments, thus evidencing fewer binding points and indicating that the product is significantly different from the instantly disclosed product.

Applicant's arguments that the following references do not teach an activation step of the polymer prior to treating the activated polymeric material with a hydrophilic polymer in the presence of an initiator or catalyst and that the products obtained would, therefore, not be the same as the instantly claimed products are found persuasive and the rejections have been withdrawn. See paper number 7, pages 12-16, 18-19. The rejections of claims over each of J 1248460, J 11007937, JP 4136267, Janssen (4,678,838) and Zhang et al (5,889,073) are hereby withdrawn.

Applicant's argument that the following references do not teach the method step of treating the activated polymeric material with a hydrophilic polymer in the presence of an initiator or catalyst has

been found persuasive. The rejections over each of J 11067183, J 09012752, JP 09143884, JP4253231, Valint, Jr. et al (6,213,604), Grobe, III et al (6,200,626), J 07090783, and Young, Sr. et al (5,432,000) with respect to the method claims have been withdrawn. It is noted that J '267 teaches treatment with a rubber latex, not a hydrophilic polymer. Applicant's argument that the instantly claimed product is different from the prior art products obtained by graft polymerization of hydrophilic monomers onto an activated polymeric material is persuasive. These products do not comprise a hydrophilic polymer bonded to the activated polymeric material in the presence of an initiator or catalyst. Applicant's argument that graft polymerization of vinyl monomers on the activated polymeric material results in grafted polymer chains bound to the polymeric material only at the chain end is persuasive.

With respect to J '752, it is agreed that no initiator or catalyst is mentioned in the Abstract for use in the step of coating with a hydrophilic polymer after corona discharge treatment of the polystyrene substrate. Applicant argues that J '752 does not disclose activation of the polymer to make chemical bonds. This argument is not persuasive because J '752 clearly teaches forming hydrophilic groups on the polystyrene sheet by corona discharge (an activation step) followed by coating the treated polystyrene with a polymer having hydrophilic groups. There is no evidence of record to show that the product obtained in the absence of an initiator or catalyst by the method taught by J '752 is significantly different from the instantly claimed product. The hydrophilic groups on the polystyrene substrate and on the hydrophilic polymer would be expected to initiate chemical bonding.

With respect to J '884, applicant alleges that the product obtained would be different from the instantly claimed product because no initiator or catalyst is used in the step of treatment with a hydrophilic polymer. This argument is not persuasive for the following reasons. The Abstract discloses activation by plasma treatment of the polymer synthetic fibers treated with polysiloxane before treating the surface with hydrophilic resin. The plasma treatment of the polysiloxane coated polymeric fibers would be expected to provide many active sites for reaction with the hydrophilic resin, in the absence of

evidence to the contrary. The product obtained would be expected to be encompassed by the instant claims because there is no evidence of record to show that a significantly different product is obtained in the presence of an initiator or catalyst other than the activated polymer itself.

With respect to J '231, Applicant alleges that the product obtained would comprise graft polymers from each active point on the PTFE while the instantly claimed product has a hydrophilic polymer chemically bound to the functional groups on the activated surface of the polymeric material with a considerable number of binding points. However, there is no comparative evidence of record to support this allegation. The plasma treatment of the PTFE would be expected to provide many active sites for binding the hydrophilic polymer, in the absence of evidence to the contrary.

With respect to Valint, Jr. et al or Grobe, III et al, applicant argues that the reference does not teach a step of treatment with a hydrophilic polymer in the presence of an initiator or catalyst. It is agreed that the only initiator taught is the plasma treated silicone base that would be expected to function as an initiator because of the activated sites. The product obtained would be expected to correspond to the instantly claimed product because it has a carbon polymer layer made hydrophilic by plasma oxidation treatment. The product can also include attached hydrophilic polymer chains obtained by grafting.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 32, line 7, it is not clear what is meant by or encompassed by "carbon materials"? What 'carbon materials" other than those already recited in the claim are intended to be set forth? Polyolefins and other

polymers of vinyl compounds are already set forth. It is noted that applicant discloses "polyacrylonitrile fiber" as a "carbon fiber" on page 26.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 46-59 are drawn to polymeric materials obtained by the method of claim 28. The product by process claims are considered to read on prior art products that are produced by a different method wherein the product is reasonably expected to be the same in the absence of evidence to the contrary. With respect to claims 48-53, 55, 56 and 59, although the claims recite "wiping/cleansing material", "filter mediums", etc., each claim, as written, requires only the presence of a polymeric material obtained by the method of claim 28.

Claims 28, 32, 33, 34, 35, 46, 48-53, 55 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Ikada et al (4,743,258). Ikada et al disclose a polymeric base material with a hydrophilic polymer attached thereto. A method comprising activating the polymeric base material is taught in column 2, lines 51-67. Ikada et al teach attaching a previously prepared polymer to the base material by reacting reactive groups on the polymer with reactive groups on the base (column 3, lines 12-21). See Example 6. Ikada et al specifically teach medical products.

Claims 46-53, 55, 56 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by J 11067183. J '183 discloses a polyolefin treated with a hydrophilic resin in the presence of a persulfate initiator. The hydrophilic resin would be expected to be bonded to the polyolefin when treated in the presence of the persulfate initiator. There is no evidence of record to show that the product obtained is

significantly different from the instantly claimed product obtained by activation of the polyolefin before reaction with the hydrophilic resin. J '183 specifically teaches a separator.

Claims 46, 53, 55 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by JP09012752. J '752 discloses applying a corona discharge treatement to a polystyrene sheet and coating the treated sheet with a polymeric material having hydrophilic groups. See the Abstract. J '752 clearly teaches forming hydrophilic groups on the polystyrene sheet by corona discharge (an activation step) followed by coating the treated polystryene with a polymer having hydrophilic groups. The hydrophilic groups on the polystyrene substrate and on the hydrophilic polymer would be expected to form bonds. It is the examiner's position that the activated polystyrene provides an "initiator" for the reaction between the two polymers, in the absence of evidence to the contrary. There is no evidence of record to show that the product obtained in the absence of an initiator or catalyst by the method taught by J '752 is significantly different from the instantly claimed product.

Claims 46, 48, 50-53, 55, 56 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 09-143884. J '884 discloses a synthetic fiber cloth to which a polysiloxane has been applied which is treated by a plasma treatment and then by applying a hydrophilic resin to the treated cloth. The product obtained would be expected to correspond to the instantly claimed product because the hydrophilic resin would be expected to bond to the activated fiber cloth in the absence of an additional initiator or catalyst, in the absence of evidence to the contrary.

Claims 46, 48-53, 55 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by JP4253231. J '231 discloses a highly functional film comprising a water-soluble vinyl polymer bonded to the surface of plasma treated polytetrafluoroethylene. The product obtained would be expected to

correspond to the instantly claimed product because the water-soluble vinyl polymer is bonded to the PTFE material. There is no evidence of record to show that a significantly different product is obtained in the presence of an initiator or catalyst other than the plasma treated PTFE.

Claims 46, 50, 51, 53, 55 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Valint, Jr. et al (6,213,604). Valint, Jr. et al disclose plasma oxidation treatment of a silicone material followed by plasma polymerization of a hydrocarbon monomer to provide a polymeric hydrocarbon layer that is further treated with plasma to render it hydrophilic or treated by attachment of hydrophilic polymer chains. See the Abstract, column 3, lines 38-67, column 4, line 59, to column 5, line 12. The product is a contact lens having a hydrophilic polymeric coating on a silicone base.

Claims 46, 50, 51, 53, 55 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Grobe, III et al (6,200,626). Grobe et al disclose plasma oxidation treatment of a silicone material followed by plasma polymerization of a hydrocarbon monomer to provide a polymeric hydrocarbon layer that is further treated with plasma to render it hydrophilic or treated by attachment of hydrophilic polymer chains. See the Abstract, column 3, lines 38-67, column 4, line 59, to column 5, line 12. The product is a contact lens having a hydrophilic polymeric coating on a silicone base. The plasma treatment would be expected to provide numerous active sites for chemical reaction with the hydrocarbon monomer, providing a hydrocarbon polymer on the surface of the silicone material that is made hydrophilic by further plasma treatment.

Claims 46, 48-53, 55, 56 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by JP62019207. J '207 disclose a process for treating a hydrophobic porous film with corona discharge and further treating with a solution of polyol to afford a hydrophilic property to the film. The corona discharge

treatment would be expected to provide numerous active sites for chemical reaction with the polyol, thus providing a product having a hydrophilic polymer chemically bonded to the hydrophobic porous film, in the absence of evidence to the contrary.

Claims 46, 48-53, 55-57 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Young, Sr. et al (5,432,000). Young, Sr. et al disclose a process comprising pretreatment of synthetic or natural fibers by corona discharge or ozone/oxygen bleaching that results in oxygen functionality on the surface of the fibers and application of polymeric binders to the fibers. Initiators or catalysts other than the activated fibers are not mentioned. See column 8, line 28, to column 10, line 24, column 13, lines 36-59, column 23, lines 49-52, column 24, lines 21-31 and lines 53-57, column 25 lines 6-11, column 26, lines 1-17. The product obtained by the process disclosed by Young, Sr. et al would be expected to be polymeric fibers having polymeric binders chemically bound to the fibers by reaction with the oxygen functionality thereon, in the absence of evidence to the contrary.

With respect to the product claims included in the rejections set forth above, the burden is hereby shifted to applicant to establish by effective argument and/or objective evidence that the prior art product(s) or process(es) do not necessarily possess the characteristics of the claimed products or processes. Note In re Spada, 911 F. 2d 705, 709, 15 UPQ2d 1655, 1658 (Fed. Cir. 1990): "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not". Note In re Best, 562 F. 2d775, 195 USPQ 433 (CCPA 1977): "Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product". Note In re Fitzgerald, 205 USPQ 594 (CCPA 1980): The reference discloses all the limitations of the claim(s) except a property or function and the examiner cannot determine whether or not the reference inherently possesses properties

or functions which anticipate the claimed invention. See MPEP 2112-2112.02. Note In re Marosi, 710 F 2d 799, 218 USPQ 289 (Fed. Cir. 1983) and In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985): The reference teaches a product that appears to be the same as the product set forth in the product by process claims, although produced by a different process. See MPEP 2113.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28-46, 48-53, 55-57 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (6,358,557) in view of Ikada et al '258. Wang et al disclose graft polymerization of substrate surfaces by exposing the substrate to an initiator to generate reactive radical sites on the surface, contacting the substrate with a composition comprising monomer(s) and grafting the monomers onto the substrate. The products are said to be particularly suitable as medical products. A variety of substrates that can be in a variety of shapes or forms are said to be suitable for the disclosed method. See column 5, lines 52, to column 6, line 14. Solvents are taught in column 8, lines 9-29. Initiators are taught in column 8, line 50, to column 9, line 51. Ikada et al disclose polymeric materials comprising a polymeric base material with an attached polymer for use in medical devices. The polymeric material is made by activating the polymeric base material and reacting it with the polymer to be attached.

It would have been obvious to one skilled in the art at the time of the invention to employ the material taught by Ikada et al as the substrate for graft polymerization by the method disclosed by Wang et al. One of ordinary skill in the art at the time of the invention would have been motivated by a

reasonable expectation of successfully providing a useful coated medical product. Wang et al provide motivation by teaching that a variety of substrates are suitable for the method of graft polymerization disclosed. Ikada et al provide motivation by teaching a polymeric material useful for preparing a vascular prosthesis.

Claims 28-46, 48-53, 55-57 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valint et al or Grobe, III et al '626 in view of Ikada et al. Valint et al and Grobe, III et al each teach surface treated silicone medical devices wherein the substrate is activated, a polyhydrocarbon layer is formed on the substrate and then unsaturated monomers are grafted onto the activated hydrocarbon surface. Grafting initiators are taught in column 12, lines 45-62. Ikada et al disclose polymeric materials comprising a polymeric base material with an attached polymer for use in medical devices. The polymeric material is made by activating the polymeric base material and reacting it with the polymer to be attached.

It would have been obvious to one skilled in the art at the time of the invention to employ the material taught by Ikada et al as the substrate for graft polymerization by the method disclosed by Valint et al or Grobe, III et al. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of successfully providing a useful coated medical product. Valint et al and Grobe, III et al each provide motivation by teaching that a variety of substrates are suitable for the method of graft polymerization disclosed. Ikada et al provide motivation by teaching a polymeric material useful for preparing a medical device.

Claims 28-46, 48-53, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bamford et al (5,453,467) in view of Ikada et al. Bamford et all disclose a method of grafting monomers to a polymer substrate to provide a biocompatible material. Bamford et la teach that the disclosed process can be used with many known polymer types and teaches using initiators such as cerium ammonium

nitrate or a persulfate. See column 5, line 14, to column 6, line 51. Ikada et al disclose polymeric materials comprising a polymeric base material with an attached polymer for use in medical devices. The polymeric material is made by activating the polymeric base material and reacting it with the polymer to be attached.

It would have been obvious to one skilled in the art at the time of the invention to employ the material taught by Ikada et al as the substrate for graft polymerization by the method disclosed by Bamford et al. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of successfully providing a useful coated medical product. Bamford et al provide motivation by teaching that a variety of substrates are suitable for the method of graft polymerization disclosed. Ikada et al provide motivation by teaching a polymeric material useful for preparing a medical device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W Berman whose telephone number is 703 308 0040. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 703 308 2462.

The fax phone numbers for the organization where this application or proceeding is assigned are 703 872 9310 for regular communications and 703 872 9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0661.

Susan Berman

Susan W Berman

Primary Examiner

Art Unit 1711

SB
08/7/03